MAY 2 5 2001

K011381

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:
Hummer IV MicroDebrider System

General Information

Proprietary Name:	Hummer IV MicroDebrider System
Common Name:	Hummer IV 21 CFR 874.4250 Ear, Nose and Throat Electric and Pneumatic Drill
Proposed Regulatory Class:	Class II Class I exempt (accessories)
Device Classification:	77 ERL
Submitter:	Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 877-534-2464 x3295
Submitter's Registration #:	1811755
Manufacturer's Registration #:	1811755 (Handpiece) 2648666 (Accessories)
Contact Person:	Robin L. Rowe Regulatory Affairs Associate Telephone: 877-543-2464 x3295 Fax: 616-324-5458
Summary Preparation Date:	May 1, 2001

Intended Use

The subject device, Hummer IV MicroDebrider System, is to be utilized for Functional Endoscopic Sinus Surgery (FESS) for the incision of soft and osseous tissue in the sinus cavities, open plastic, reconstructive and aesthetic surgery of the Head and Neck. This system is indicated for exactly the same uses as the cleared K972584 Hummer II MicroDebrider System (TPS), K952681 Hummer II MicroDebrider System and K940710. This Special 510(k) submission is due to the design changes of the handpiece.
See Appendix C for equivalency.

Device Description

System Hardware - Console, Handpiece and Footswitch

The Stryker Hummer IV System consists of electrically powered instrumentation specifically designed for the debridement of soft and hard tissues. The console provides the power necessary to drive a motorized hand piece to rotational speeds equivalent to the industry standards and a peristaltic pump. A footswitch is used to provide forward, reverse and oscillating control over the handpiece, and variable flow rates for the pump. The handpiece drives irrigated cutters, burs and rasps, and is designed to provide suction control for surgeon convenience. A variety of cutters, burs and rasps are available to meet the needs of the surgeon. The specification and drawings for the hardware are shown in Appendix A.

The console provides the power to drive the handpiece and the pump located on the console. The pump is a peristaltic type pump which features a rotating clamping mechanism to hold the disposable tubing set in place. Connectors on the console are used to attach the footswitch and handpiece. The input from the footswitch determines the speed and direction of the handpiece and the speed of the pump. The pump is able to provide irrigation to the cutters, burs and rasps in two different manners. When the handpiece is activated the pump is simultaneously activated providing irrigation to the cutter/bur/rasp which may also be activated independently of the handpiece to provide irrigation to the surgical site while suction is once again controlled at the handpiece. The pump can be turned off at the console at the surgeon's discretion.

A footswitch is utilized to control electrical signals to the console. The functions provided on the footswitch include; variable speed for the handpiece, mode selection for the handpiece (forward, reverse or oscillate), pump on/off control and variable speed for the pump. A cable is used to connect the footswitch to the console and the electrical components are sealed to protect them from moisture.

The handpiece is an electrically driven motor design. An ergonomically designed handpiece has a quick release coupling mechanism to secure cutters, burs or rasps. A quick locking mechanism fitting on the handpiece is used to connect the irrigation tubing to the handpiece. A valve is used for suction control and tapered fitting is utilized for attaching the suction tubing to the handpiece. The cable is attached to the handpiece, which will connect to the console. Additional handpieces may provide permanent means for spatial tracking in the surgical environment. The handpiece is designed to provide speeds in accordance with industry standards.

Disposable Accessories

The sterilized disposable accessories to be used with the Hummer IV System include cutters, burs, rasps and a suction/irrigation tube set. These accessories are gamma or ETO sterilized to a SAL of 10-6, and is cleared under K952681 and K940710 for sinus surgery. Refer to Appendix A for drawings.

The tubing set is used to provide irrigation to the cutter and suction to the handpiece. The suction and irrigation tubing are separate.

Substantial Equivalence

EQUIVALENT PRODUCTS:

The Hummer IV MicroDebrider System is identical to the named device in all respects with the exception of the ergonomic handpiece design with rotational speeds equivalent to industry standards. The handpiece has a modified suction path that will provide a more comfortable grip for the user. Additional handpieces may provide permanent means for spatial tracking in the surgical environment. This system will be compatible with Stryker's burs, cutters and rasp accessories.

Robin L. Rowe
Regulatory Affairs Representative
May 1, 2001

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 5 2001

Mr. Robin L. Rowe
Regulatory Affairs Representative
Stryker Leibinger
4100 East Milham Avenue
Kalamazoo, MI 49001

Re: K011381
Trade Name: Hummer IV MicroDebrider System
Regulatory Class: II
Product Code: 77 FRL
Dated: May 1, 2001
Received: May 7, 2001

Dear Mr. Rowe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K011381

Device Name: Hummer IV MicroDebrider System

Indication For Use:

The Hummer IV MicroDebrider System

The subject device, The subject device, Hummer IV MicroDebrider System, is to be utilized for Functional Endoscopic Sinus Surgery (FESS) for the incision of soft and osseous tissue in the sinus cavities, open plastic, reconstructive and aesthetic surgery of the Head and Neck. This system is indicated for the same uses as the cleared K972584 Hummer II MicroDebrider System (TPS), K952681 Hummer II MicroDebrider System and K940710. This Special 510(k) submission is due to the design changes of the handpiece.

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Concurrence of CDRH, Office of device Evaluation (ODE)

for DOED

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011381

Prescription Use X or Over-The-Counter Use_____
(per 21 CFR 801.109)

(Optional Format 1-2-96)